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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,376	03/04/2004	Vladimir Sabetsky	028093-0113	3029

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EXAMINER

KHANNA, HEMANT

ART UNIT PAPER NUMBER

1654

MAIL DATE DELIVERY MODE

07/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/792,376	SABETSKY, VLADIMIR	
	Examiner	Art Unit	
	Hemant Khanna	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 26-37 and 41-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-37, 41 and 42 is/are rejected.
- 7) ☒ Claim(s) 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to Applicant's remarks filed April 27, 2007. While the Examiner respectfully acknowledges Applicant's amendment to claims 26-27, 35-37. The Examiner further acknowledges the addition of new claims 41-45.
2. The Examiner respectfully submits that claims 26-37 as originally filed were rejected under 35 USC 103. The Applicant has argued the obviousness rejections in light of the amendment to claim 26.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.
4. Claims 26-37, 41-45 are pending.
5. Claims 26-37, 41-42 are rejected under 35 USC 103 as set forth below.

Claim Rejections - 35 USC § 103

6. (Maintained) Rejection of claims 26-37, 41-42 under 35 U.S.C. 103(a) as being unpatentable over Schroder (USPN 4,713,249) in view of Ecanow (USPN 4,963,526) and Moriyama (Journal of Controlled Release (1996) 42:237-248, as cited in the IDS filed on August 20, 2006) is maintained for reasons of record and for reasons set forth below.

The instant claims are drawn to a pharmaceutical composition, comprising dextran microparticles in presence of insulin, wherein the composition comprises two phases of dextran and PEG, and further wherein the insulin is selectively partitioned in the PEG phase.

The Applicant's argue that the instant composition is different from Schroeder's because the process of Schroeder leads to encapsulation of biologically substances (Remarks, page 5, last paragraph) which is distinct from the process of instant invention wherein the microparticles are crystallized prior to being combined with insulin (Remarks, page 6, last paragraph). The Applicant's also argue that Schroeder's composition cannot teach the properties of timed release of an active agent because during the preparation of Schroder the active agent is encapsulated by the carbohydrate sphere (Remarks, page 7, paragraph 2). The Applicant's further argue that amended claim 26 now recites a composition having a porosity of at least 10% by volume, which is not disclosed in combination of Schroder and Ecanow (Remarks, page 4, paragraph 4).

The Applicant's arguments have been fully considered but are not found persuasive.

The references of the prior art as disclosed previously and as set forth below are-
Schroeder teaches prolonged release compositions for the delivery of biologically active substances, such as insulin (Example 13) consisting of a carbohydrate

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microsphere, such as dextran (column 3, lines 4-20; Example 1), wherein the carbohydrate is stabilized by crystallization (abstract). Schroeder further teaches that in crystallization, the types of bonds holding the carbohydrate polymers are non-covalent of the type hydrogen bonds or vander Waals forces (column 2, lines 55-60). Schroeder also teaches that during the preparation of the composition, the carbohydrate polymer is dissolved in a pharmaceutically acceptable solvent, such as water (column 3, lines 60-70). Schroeder also discloses that the average diameter of the spheres is within a range of 0.01 microns to 1000 microns.

Ecanow discloses that it is known in the art to provide a composition in oral dosage form such as capsules, tablets or a liquid vehicle (claim 35) wherein a dose of insulin is useful for introduction in the bloodstream via the oral dosage form (claim 36).

Moriyama discloses that it is known in the art to distribute proteins in a two-phase system by mixing aqueous solutions in phosphate buffer of two different water soluble polymers, such as PEG and dextran, and insulin, wherein the negatively charged insulin is preferentially partitioned into the PEG phase (second paragraph, page 238; Figure 1)

The Applicant is reminded that instant claim 26 as originally filed or as amended, is drawn to a composition. While Applicant has argued the preparation of the instant invention by a process distinct from the prior art, the Examiner respectfully submits that the determination of patentability of a product claim is based on the product and not on the process utilized to obtain the product. Hence the Applicant's arguments on the

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preparation of the compositions to render the said composition unobvious are moot.

See MPEP 2113.

Further, the Examiner respectfully submits that in view of the amendments to claim 26, the disclosure of Schroder suggests a motivation for one of ordinary skill in the art to utilize a varying degree of porosity in the polymer preparation in order to obtain varying release times" (column 2, lines 28-32). While Schroder does not explicitly recite "a porosity of 10% by volume", it is merely a matter of judicious selection and routine optimization for one of ordinary skill in the art at the time of the invention to make adjustments to the degree of porosity. There would have been a reasonable expectation of success in producing the claimed invention for the known and expected result of providing a means for the prolonged release of the biological agent over an extended period of time, especially in the absence of evidence to the contrary.

Given the content of the prior art and the motivation to combine references as disclosed in Schroder, Ecanow and Moriyama, the instantly claimed invention of a pharmaceutical composition comprising dextran microparticles and insulin is unpatentable. As discussed above, the differences between it and the prior art are not sufficiently great that the subject matter as a whole would not have been obvious at the time the invention was made by one of ordinary skill in the art.

Rejection is maintained.

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Claim Objections

4. Claims 44-45 are free of the prior art. Claim 43 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant Khanna whose telephone number is (571) 272-

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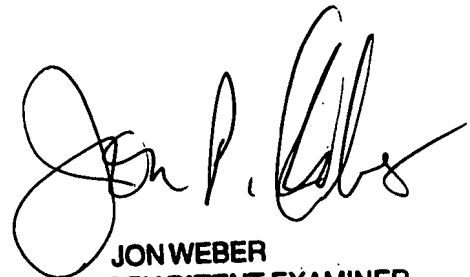
9045. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Hemant Khanna Ph. D.
June 28, 2007



JON WEBER
SUPERVISORY PATENT EXAMINER